K062033/S2
p1/3

510(k) Summary

1. **Submitter's Name:** Mr. Dacheng Gong, Manager

MAR 23 2007

KINGYIELD HONGKONG LIMITED

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Contact: Mr. Dacheng Gong, Manager

Date of Summary: Jan. 18 2006

2. Trade Name: BP101 Digital Blood Pressure Monitor

3. Classification Name

Non-invasive Blood Pressure Measurement System.

Regulation Number: 21 CFR 870.1130

Class: II

4.Product Code: DXN

5.Classification Panel: Cardiovascular

6. Predicate Device: HEM-757 Automatic Digital Blood Pressure Monitor with Intelligence marketed by Omron Healthcare INC.

K 001670 (Predicate)

7.**Device Description:**

BP101 Digital Blood Pressure Monitor is a fully automatic non-invasive blood pressure monitor which measures systolic and diastolic blood

pressure and heart rate of adult population using the oscillometric method by inflating an inflatable cuff on the upper arm.

The Intended use:

BP101 Digital Blood Pressure Monitor is intended to be used to measure blood pressure (systolic and diastolic) and heart rate from the upper arm using the oscillometric method.

The device is intended for use in only adult population, not applied to the other populations such as neonatal baby.

It can not be used while the arm has bleeding or wound to avoid the blood flowing from the wound in pressurizing.

8. Performance and Technological Characteristics :

8.1 Performance Summary

In terms of operating specification, Safety & EMC requirements, the device conform to applicable standards including ANSI/AAMI SP-10:2002, EN 1060-1, EN-1060-3, and IEC60601-1-1-2 requirements.

A comparison study with a device that uses auscultatory method used by trained observers was performed to validate the performance of BP101. The comparison study demonstrated that the clinical repeatability of BP101 is statistically and clinically acceptable.

8.2 Technological Characteristics

BP101 Digital Blood Pressure Monitor uses an inflated cuff which is

The systolic and diastolic blood pressures are determined by Oscillometric method. The deflation rate is controlled by an automatic air-release valve at a constant rate 2~7mmHg/second. The user can deflate the cuff to stop measuring by pressing the "START/STOP" button at any time while measuring. The measuring result is displayed in LCD.

9.**Conclusion**

BP101 Digital Blood Pressure Monitor has the same intended use, the same technological characteristics as the predicate device HEM-757, Moreover, non-clinical testing & clinical testing contained in this submission demonstrated that any difference in their technological characteristics doesnot raise any new issues of safety and effectiveness. In a word, BP101 is substantial equivalent to the predicate device HEM-757.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 23 2007

Welch Allyn Protocol, Inc.
c/o Mr. Tamas Borsai
Program Manager, Third Party Review Program
12 Commerce Rd.
Newton, CT 06470

Re: K062033
Trade/Device Name: BP101 Digital Blood Pressure Measurement System
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive blood pressure measurement system
Regulatory Class: Class II (two)
Product Code: DXN
Dated: March 8, 2007
Received: March 12, 2007

Dear Mr. Borsai:

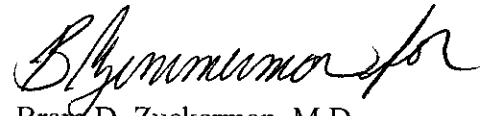
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062033/S2

Indications for Use Statement

510(k) Number (if known): K062033

Device Name: BP101 Digital Blood Pressure Monitor

Indications For Use:

It can be used as medical assistant instrument at home or in medical center for adult population for measuring systolic and diastolic blood pressure and heart rate.

The device is intended for use in only adult population, not applied to the other populations such as neonatal baby.

It can not be used while the arm has bleeding or wound to avoid the blood flowing from the wound in pressurizing.

Prescription Use _____ AND/OR Over-The-Counter Use ✓ (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062033